



# A Prospective Evaluation of Cerebral Infarction following Transcervical Carotid Stenting with Carotid Flow Reversal

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## KEYWORDS

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**Abstract** *Objective:* Cerebral embolisation constitutes the main source of complications during transfemoral carotid artery stenting (CAS) and is associated with a high incidence of silent brain infarction. The goal of this study is to evaluate the incidence of new ischaemic cerebral lesions following transcervical CAS with carotid flow reversal for neuroprotection.

*Materials and Methods:* Thirty-one consecutive patients underwent transcervical CAS with carotid flow reversal. A stroke scale and diffusion-weighted magnetic resonance imaging (DW-MRI) were performed within 24 h before and after the procedure. DW-MRI studies were compared blindly by two independent neuroradiologists. New hyper-intense DW signals were interpreted as ischaemic infarcts. The progress of all patients was followed for at least 30 days following intervention.

*Results:* All procedures were technically successful. Nineteen (61%) patients were symptomatic. Mean carotid flow reversal time was 22 min. There were no major adverse events at 30 days. All patients remained neurologically intact without increase in the stroke scale. Thirty subjects had paired DW-MRI studies. Post-procedural DW-MRI ischaemic infarcts were found in four (12.5%) patients, all ipsilateral to the treated hemisphere and asymptomatic. During follow-up, all stents remained patent and all patients remained stroke-free.

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**Conclusions:** These data suggest that transcervical carotid stenting with carotid flow reversal carries a low incidence of new ischaemic infarcts, significantly lower than that reported with transfemoral CAS. The transcervical approach with carotid flow reversal may improve the safety of CAS and has the potential to produce results comparable to those of carotid endarterectomy.

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Carotid endarterectomy (CEA) has been a mainstay in the treatment of carotid artery disease and has been shown to reduce the risk of stroke in randomised trials. Carotid artery stenting (CAS) via a transfemoral access route offers a new treatment option for significant carotid stenosis. The current literature favours the use of cerebral protection methods during CAS and suggests that cerebral protection devices may reduce stroke rates compared with unprotected CAS. However, to date no prospective trial has proven that cerebral protection methods improve the results of CAS, and the different available protective methods have not been compared in a prospective fashion.

The low incidence of clinically apparent neurological complications during CAS is in stark contrast with the high incidence of silent brain infarction demonstrated by diffusion-weighted magnetic resonance imaging (DW-MRI) following the procedure. The potential relationship between silent brain infarction and long-term deterioration in cognitive function and/or development of dementia remains an unresolved concern.

A recent study suggests a slightly lower incidence of post-procedural silent infarctions when cerebral protection is used during CAS, compared with unprotected CAS.<sup>1</sup> Our study was designed to evaluate prospectively the incidence of new cerebral ischaemic lesions, as assessed by DW-MRI during CAS, performed through a transcervical access approach using carotid flow reversal for cerebral protection.

## Materials and Methods

From April 2008 to June 2009, 31 consecutive patients with significant carotid stenosis were included in the study. The study inclusion criteria required an accepted indication for carotid intervention, carotid bifurcation located at least 5 cm from the edge of the clavicle; absence of calcification in the anterior wall of the common carotid artery and no contraindication for DW-MRI.

The degree of carotid artery stenosis was evaluated by ultrasonography following NASCET criteria (NASCET, The North American Symptomatic Carotid Endarterectomy Trial).<sup>2</sup> Carotid plaques were categorised into echolucency type according to Geroulakos.<sup>3</sup> Intra-operative angiography was used in all cases to confirm the degree of the stenosis.

All patients signed an informed consent form and the study was conducted in accordance with the institution's review board for research involving human subjects following institutional guidelines.

## Surgical technique

All patients were treated preoperatively with aspirin and clopidogrel. All procedures were performed by vascular

surgeons experienced in CAS, and done under local anaesthesia with clinical monitoring of neurological function. Systemic anticoagulation was conducted before carotid occlusion giving 100 units of intravenous heparin per kilogram of body weight. Heparin was not reversed with protamine at the completion of the procedure.

Our surgical technique has been published before.<sup>4</sup> Briefly, it consists of a short incision above the edge of the clavicle between the heads of the sternocleidomastoid muscle. A short segment of the common carotid artery and jugular vein are dissected, and the common carotid artery is controlled with a Rummel loop. Eight-French sheaths are placed in the jugular vein and the common carotid, and connected to establish a carotid-to-jugular fistula.

Flow reversal is established and functioning of the fistula is ascertained by arteriography, a 0.014-inch guidewire is used to cross the carotid lesion. Before balloon dilatation, 1 mg of intravenous atropine is administered.

Lesion pre-dilatation was deemed necessary in eight cases (26%) in which the lesion would not allow easy passage of the stent delivery system. Pre-dilatation was performed with carotid flow reversal using 3–4-mm, 2-cm-long balloons inflated to 10 atm (Ultra soft SV<sup>®</sup> Monorail Balloon catheter; Boston Scientific, MA, USA). Self-expandable Wallstents<sup>®</sup> were used in 25 cases (Boston Scientific, Massachusetts, USA) and Protege<sup>®</sup> stents in six (EV3 endovascular, Minnesota, USA). Stent selection was based on lesion characteristics and surgeon preference. All stents were post-dilated to 10 atm with 2-cm-long balloons with balloon diameters ranging from 5 to 7 mm (Ultra soft SV<sup>®</sup> Monorail Balloon catheter; Boston Scientific, MA, USA). Post-dilatation mean duration was 4 s with a standard deviation of 2 s. Completion angiogram was done in all cases including anteroposterior, oblique and lateral intracranial projections.

After post-dilatation the introducers were withdrawn and the vessels closed with polypropylene sutures of 5/0 or 6/0. A small Penrose drain was placed and the wound closed with absorbable suture.

Technical failure was defined as the inability to complete the procedure for any cause.

## Neurological evaluation

DW-MRI was acquired with sagittal T1 sequences, T2 W axial, FLAIR axial and ADC map. In addition, T1 W axial and sagittal were conducted after contrast administration. DW-MRIs were conducted within 24 h before and within 24–48 h after the procedure. Pre- and post-operative DW-MRIs were read by two independent neuroradiologists (BL and CL), unaware of the patient's clinical status and blinded to the timing (pre- or post-) of the paired scans. Ischaemic lesions

in both cerebral hemispheres were recorded by each reader and compared to that of the second reader. Discrepancies were reviewed and reconciled.

All patients were evaluated by a neurologist before and after the procedure using the Rankin stroke scale. Neurological deficits lasting more than 24 h were defined as stroke while those lasting less than 24 h were defined as transient ischaemic attacks (TIAs). All patients were reviewed 30 days after surgery, with a clinical assessment and carotid scanning.

## Results

Thirty-one consecutive patients with carotid stenosis with a mean age of 68 years entered this study. Twenty-seven patients were men and four women. Nineteen patients (61%) were symptomatic, 11 patients with TIA and eight with stroke. Five patients had a high degree of contralateral CAS and one of these had a complete occlusion. The treated carotid was the right in 18 cases and the left in 13. There were no bilateral interventions. Carotid plaque echolucency is detailed in Table 1. Co-morbid conditions are detailed in Table 2.

All procedures were technically successful without (>30%) residual stenosis. The degree of carotid stenosis assessed by arteriography was 50–70% in three patients (all three patients were symptomatic), 70–90% in 23 and >90% in 5. The mean operative time was 53 min (SD 5 min) with a mean flow reversal time of 22 min (SD 4.75 min). No neurological changes were noted during the procedure in any patient. Following intervention, there were no strokes or TIAs. The Rankin stroke scale did not deteriorate in any patient and actually improved in five. No wound complications occurred in any patient.

New post-procedural DWI-MRI-detected cerebral ischaemic lesions were found in four subjects, all of whom had paired DWI-MRIs. These patients developed one, two or five ischaemic lesions in the white matter of the ipsilateral hemisphere smaller than 5 mm in diameter without evidence of stroke or TIA. One patient with two new ischaemic lesions had dislodgement of the carotid sheath during the procedure with loss of flow reversal until the sheath was replaced. The remaining subjects had completion of the procedure with flow reversal maintained throughout the intervention. Intolerance to carotid flow reversal was not detected in any patient, even in those with contralateral carotid stenosis >50%.

## Discussion

DW-MRI is sensitive and specific in the detection of acute cerebral ischaemia,<sup>5</sup> revealing hyper-intense signals in the

**Table 2** Comorbid Conditions.

	<i>n</i>	%
Hypertension	24	77.4
Diabetes Mellitus	11	35.5
Hyperlipidemia	17	54.8
Previous Myocardial Infarction	7	22.6
Smoking within last 6 months	8	25.8
Peripheral Arterial Disease	5	16.1

affected areas.<sup>6</sup> Aortic arch instrumentation during diagnostic procedures could produce an incidence of silent ischaemic brain infarcts as high as 26% in the hemisphere under study, and also in the contralateral hemisphere.<sup>7</sup>

This concerning incidence of cerebral embolisation during carotid instrumentation prompted the study of ischaemic brain infarction following CAS using DW-MRI. A systematic review of the literature by Schnaudigel *et al.*<sup>1</sup> involving 1363 CAS and 754 CEA procedures suggested evidence of new cerebral ischaemic lesions at rates of 37% and 10% ( $p < 0.01$ ), respectively. Protection devices modestly reduce the incidence from 45% to 33% ( $p < 0.010$ ).<sup>1</sup> The incidence of new ischaemic lesions in the contralateral hemisphere (0.01% in CEA vs 14.5% in CAS;  $p < 0.01$ ) was significantly greater after transfemoral CAS, suggesting embolisation during aortic arch manipulation. The incidence of brain infarction during transfemoral CAS and CEA is summarised in Tables 3 and 4. However, these data are based on self-audited non-randomised case series of protected CAS versus unprotected stenting. Data from two recently published randomised controlled trials comparing filter-protected versus unprotected CAS questioned routine filter use, which may be associated with a higher incidence of new emboli after CAS compared with control groups.<sup>42,43</sup>

Our incidence of new cerebral ischaemic lesions on DW-MRI using transcervical CAS with carotid flow reversal suggests that it is superior to transfemoral CAS and is comparable to CEA. Transcervical CAS with carotid flow reversal has a technical success rate of 97%, a zero incidence of major stroke or death, a 91% stroke-free survival at 3 years<sup>44</sup> and a remarkable absence of embolic signals detected by transcranial Doppler during the procedure.<sup>45</sup> In our study population of 31 patients, 61% were symptomatic. Despite our higher proportion of symptomatic patients, the 30-day major neurological complication rate remained zero. Similar to the experience with carotid endarterectomy, we did not observe new infarcts in the contralateral hemisphere during our study. This most likely reflects the lack of aortic arch and proximal supra-aortic trunk manipulation.

Current transfemoral stenting experiences exhibit rates of emboli as high as 70% which can be improved by minimising trauma during access.<sup>29,46</sup>

Proximal protection devices, delivered transfemorally, use the same reverse flow protection as the technique we describe. However, they require manipulation in the aortic arch, great vessels and carotid bulb during periods of the procedure when there is no cerebral protection. In comparison, our technique uses a low cervical incision,

**Table 1** Carotid plaque morphology according to echolucency criteria.

Plaque morphology	Number of plaques
Type 1	2
Type 2	9
Type 3	9
Type 4	10
Type 5	1

**Table 3** Incidence of Ischemic Infarction with Carotid Artery Stenting.

Author	Year	Procedures (N)	Strokes (N)	New Ischemic lesions on DW-MRI		
				Ipsilateral	Contralateral	Any
Lovblad <sup>8</sup>	2000	19	2			4 (21,05%)
Jaeger <sup>9</sup>	2001	20	0	3	2	5(25 %)
Jaeger <sup>10</sup>	2002	70	1	20	6	26 (37,14%)
Schluter <sup>11</sup>	2003	44	1	8	2	10 (22,72%)
Gauvrit <sup>12</sup>	2004	22	1	2	0	2 (9,09%)
Poppert <sup>13</sup>	2004	41	1	22	4	22 (53,65%)
Flach <sup>14</sup>	2005	21	1	9	2	9 (42,85%)
Roh <sup>15</sup>	2005	18	2			8 (44,44%)
Cossottini <sup>16</sup>	2005	52	1			16 (30,76%)
Hammer <sup>17</sup>	2005	53	2	14	13	21 (39,62%)
Hauth <sup>18</sup>	2005	105	0			22 (20,95%)
Rosenkranz <sup>19</sup>	2006	27	0	6	2	8 (29,62%)
Du Mesnil <sup>20</sup>	2006	50	1	14	7	19 (38%)
Maleux <sup>21</sup>	2006	53	0	17	10	22 (41,50%)
McDonnell <sup>22</sup>	2006	107	8			23 (21,49%)
Pinero <sup>23</sup>	2006	162	1	22	9	28 (17,28%)
Kastrup <sup>24</sup>	2006	206	11	113	38	126 (61,16%)
Asakura <sup>25</sup>	2006	45	1	14	13	20 (44,44%)
Iihara <sup>26</sup>	2006	92	7			32 (34,78%)
Grunwald <sup>27</sup>	2006	10	0	3	1	4 (40%)
Rapp <sup>28</sup>	2007	54	2	35	11	36 (59,01%)
Lacroix <sup>29</sup>	2007	61	2	20	10	26 (42,62%)
Tedesco <sup>30</sup>	2007	27	2	16	10	19 (70,37%)
Skelland <sup>31</sup>	2009	30	2	6	0	6 (20%)
Taha <sup>32</sup>	2009	98	3	35	20	42 (42,85%)

thereby avoiding the arch manipulation risk, and eliminates instrumentation for external carotid artery occlusion. Additionally, it also reduces the risk of complications associated with CEA.

The clinical significance of the appearance of post-procedural silent ischaemic cerebral lesions is unknown.

Very few studies have described the long-term fate of post-operative DWI-detected ischaemic lesions. Whether these silent ischaemic lesions cause permanent brain damage with cognitive impairment or merely transient sequelae remains unclear. Indeed, some of these lesions may resolve within months, as reported in other series.<sup>47</sup> However,

**Table 4** Incidence of Ischemic Infarction with Carotid Endarterectomy.

Author	Year	Procedures (N)	Strokes (N)	New Ischemic lesions on DWI		
				Ipsilateral	Contralateral	Any
Jansen <sup>33</sup>	1994	40	1	4	0	4 (10%)
Cantelmo <sup>34</sup>	1998	78	1	7	0	7 (8,97%)
Barth <sup>35</sup>	2000	48	0	2	0	2 (4,17%)
Feiwell <sup>36</sup>	2001	25	0	1	0	1 (4%)
Forbes <sup>37</sup>	2001	18	1	0	0	0 (0 %)
Tomczak <sup>38</sup>	2001	51	0	6	0	6 (11,76%)
Müller <sup>39</sup>	2003	33	1			9 (27,28%)
Wolf <sup>40</sup>	2004	33	1	8	0	8 (24,25%)
Poppert <sup>13</sup>	2004	88	2	15	0	15 (17,04%)
Flach <sup>14</sup>	2004	23	2	2	0	2 (8,69%)
Roh <sup>15</sup>	2005	26	1	1	0	1 (3,85%)
Iihara <sup>25</sup>	2006	139	3			13 (9,36%)
Inoue <sup>41</sup>	2006	72	1			3 (4,17%)
Lacroix <sup>28</sup>	2007	60	2	7	1	7 (11,67%)
Tedesco <sup>29</sup>	2007	20	0	0	0	0 (0%)
Skejelland <sup>30</sup>	2009	61	0	2	0	2 (3,28%)

anatomical resolution may not be necessarily associated with absence of neurological sequelae.

In the absence of stroke or TIA, we do not know whether permanent cerebral damage follows these lesions, although there is increasing evidence that silent cerebral infarction is associated with a higher risk of long-term cognitive deterioration or development of dementia probably in predisposed individuals.<sup>48</sup>

Unfortunately, we were not able to include a standard cognitive assessment of our patients before and after the study to measure changes in this rather unexplored brain function. However, our low incidence of new ischaemic lesions and the small patient sample does not allow establishing correlations between potential risk factors for cerebral embolisation and long-term neurological changes. Our data strongly suggest that transcervical carotid stenting with flow reversal may produce a significantly lower incidence of cerebral embolisation than currently obtained with conventional transfemoral carotid stenting procedures.

## Conclusions

Carotid stenting using a transcervical approach with cerebral flow reversal is a very safe procedure with a very low incidence of major adverse events. The remarkably low incidence of silent brain infarctions appearing after the procedure suggests that this technique may be safer than the transfemoral approach. The low incidence of major adverse events and silent brain infarction obtained with transcervical carotid artery stenting with carotid flow reversal may be comparable to that obtained with the best results of carotid endarterectomy via a minor low incision which avoids cranial nerve injury and general anaesthesia.

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## Conflict of Interest

The corresponding author (EC) is a consultant and shareholder for Silk Road Medical, Inc. which partially funded the study.

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